

EXECUTIVE SUMMARY

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA or the Act), the Nation's primary chemicals management law, was signed into law. The new law includes statutory requirements related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to “determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use.” In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Asbestos was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for asbestos.

This document presents the scope of the risk evaluation to be conducted for asbestos. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, in conducting a risk evaluation under TSCA EPA will first identify “circumstances” that constitute “conditions of use” for each chemical. While EPA interprets this as largely a factual determination —*i.e.*, EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

In the case of asbestos, legacy uses and associated legacy disposals will be excluded from the scope of the risk evaluation. These include asbestos-containing materials that remain in older buildings or are part of older products but are no longer manufactured (including imported), processed, or distributed in commerce for that use. EPA is excluding these uses because EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on current and prospective uses, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of “conditions of use” in that context. Moreover, during problem formulation EPA may determine that not all conditions of

use mentioned in this scope will require a full risk evaluation. Any condition of use that will not be evaluated in-depth will be clearly described in the problem formulation document. In addition, it is possible that EPA will determine that conditions of use not included in this scoping document should be included in the risk evaluation, as a result of development of problem formulation.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. First, it is possible this scope document may not conform to all of the provisions of the final risk evaluation rule. Second, time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

For the purposes of scoping and risk evaluation, EPA has adopted the definition of asbestos as defined by TSCA Title II (added to TSCA in 1986), Section 202 as the *“asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.”* Asbestos is a “generic commercial designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series” (IARC 2012). The latter five fiber types are amphibole varieties. The general CAS Registry Number (CASRN) of asbestos is 1332-21-4; this is the only asbestos on the TSCA Inventory. However, CASRNs are also available for specific fiber types.

Asbestos has not been mined or manufactured in the United States since 2002; therefore, any new asbestos entering this country is imported. In 2016, the United States imported approximately 340 metric tons of raw asbestos.

EPA has identified the ongoing use of chrysotile asbestos in the chlor-alkali industry and the use of asbestos-containing sheet gaskets in the manufacture of titanium dioxide. Other uses that have been identified include asbestos containing products for ongoing commercial and consumer use. The volume of products containing asbestos that are potentially fabricated or imported in the U.S. is estimated and not definitively measured. For the purposes of the scoping document, the products were placed into use categories that include, “known use,” “evidence of use,” and “reasonably foreseen use.” These categories are represented in the initial life cycle diagram (see Figure 2-3).

The initial conceptual models presented in Section 2 include the following that EPA expects to evaluate: conditions of use, exposure pathways (e.g., media), exposure routes (e.g., inhalation, dermal, oral), potentially exposed susceptible subpopulations (e.g., workers, occupational non-user; general population; residents co-located with certain conditions of commercial use; consumer users; bystanders of consumer use; aquatic organisms, terrestrial organisms) and hazards EPA expects to evaluate based on the inherent hazards of the chemical (which will be refined based on relevancy to specific exposure scenarios). It is expected that inhalation will be the primary route of exposure to all populations.

Figure 2-4 presents the occupational scenarios in which workers and occupational non-users may be exposed to asbestos during a variety of conditions of use, such as fabrication of asbestos-containing diaphragms in the chlor-alkali industry and use of imported asbestos-containing products in industrial settings. Figure 2-5 presents the consumer model which indicates exposures occurring from asbestos containing products in either indoor or outdoor environments. EPA considers workers, occupational non-users, consumers and bystanders and certain groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use identified as potentially exposed or susceptible subpopulations. EPA will also evaluate whether groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration).

Exposures to the general population may occur from industrial releases. Only environmental releases of *friable* asbestos are reported in the Toxics Release Inventory. Most of the reported asbestos releases were to landfills, and EPA expects to consider these releases as they relate to exposures to occupational, consumer and general populations. Asbestos fibers are largely chemically inert under environmental conditions. They may undergo minor physical changes, such as changes in fiber length, but do not degrade, react, or dissolve to any appreciable extent in the environment.

Asbestos has been the subject of numerous health hazard and risk assessments, based primarily on data on human populations. Many authorities have established that there is causal association between asbestos and lung cancer and mesotheliomas. Causal associations between exposure to asbestos and cancer of the larynx and ovary have also been reported. Non-cancer hazards of asbestos include toxicity to the respiratory system (e.g., asbestosis) and immunotoxicity. These hazards will be evaluated based on the specific exposure scenarios identified.

The initial analysis plan describes EPA's plan for conducting systematic review of available information and identification of assessment approaches to be used in conducting the risk evaluation for asbestos. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of asbestos.